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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,952	10/24/2001	J. David Rozzell JR.	47418/KMO/B583	1571

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/039,952	Applicant(s) ROZZELL, J. DAVID	
	Examiner Ralph Gitomer	Art Unit 1655	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The RCE Request received 12/1/05 has been entered and claims 18, 20, 21 are currently pending in this application. The claims have not been amended.

Claims 18, 20, 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added limitation to the claims "wherein the ketone is not a 2-ketoacid and the amine is not an alpha-amino acid" is new matter. No written description for this concept is found in the specification as originally filed.

Applicant's arguments filed 12/1/05 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches the negative limitation claimed on page 11 of the specification as well as in other places.

It is the examiner's position that the specification as originally filed does not enable the concept as claimed. On page 11 lines 1-3 of the present specification, "In a particularly preferred embodiment, the target compound is a ketone that is not a ketacid, and the target compound is converted to an amine, preferably a chiral amine, in the presence of an amine dehydrogenase." This is inconsistent with the material added to the claims.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Liu in view of each of Engel and Yan.

The claims are directed to a method for producing an amine from a target ketone with an enzyme that has been mutated from a wild type enzyme. How the mutation is achieved or the result of the mutation is not claimed.

Liu (6,365,380) entitled "Method for Stereoselectively Inverting A Chiral Center of A Chemical Compound Using an Enzyme and A Metal Catalyst" teaches in column 2 lines 35-43, amino acid transaminases where keto compounds are converted to amines. In claim 1 amino acid dehydrogenase is shown.

The claims differ from the above references in that they state the enzyme is mutated.

Engel (5,798,234) entitled "Method For the Directed Modification of Enzymes, Modified Enzymes And Their Use" teaches in the abstract, modifying enzymes. In column 1 amino acid dehydrogenases were screened. In column 3 lines 44-55, modified amino acid dehydrogenases from mutants are shown. Aspartate and glutamine are substrates. In columns 6-7 a table compares wild type to mutant enzymes where the mutants have a higher activity.

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Yan (US 2003/0138930 A1) entitled "Isolated Human Dehydrogenase Proteins, Nucleic Acid Molecules Encoding These Human Dehydrogenase Proteins, and Uses Thereof" teaches in paragraph 49, generating mutants of dehydrogenases. See also paragraphs 52 and 75.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a mutated enzyme in the methods taught by the above primary references because the secondary references teach methods of making and using mutated enzymes. One of skill in this art finds it desirable to select for enzymes of specific activities under specific conditions by either selecting known enzymes or producing mutated enzymes as taught by each of the secondary references. No method of mutating or result of such mutating is claimed. No activity or conditions of the resulting enzyme is claimed.

Applicant's arguments filed 12/1/05 have been fully considered but they are not persuasive.

Applicant argues that Liu does not use mutant enzymes but enzymes that convert alpha ketoacids to amino acids and vice-versa. And Engel does not teach mutant enzymes that reductively aminate. Yan teaches alcohol dehydrogenases, not amino dehydrogenases.

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It is the examiner's position that Liu was cited to show wild type enzymes of the same type as presently claimed. Mutants of known wild types of enzymes were known in this art as shown by each of Engel and Yan. No particular characteristics of the mutant enzyme are claimed so one could not distinguish it over the enzyme taught by Liu. No novelty is seen in mutating known enzymes for well known functions with the expected result.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 18 is directed to a mutated enzyme but in what fashion or result the mutation is made is not seen in comparison with a not mutated enzyme. Claim 21 is not understood where one would not likely provide an enzyme that does not exist. Such enzymes likely exist in an organism. Further, it is directed to mutating an enzyme but does not set forth how it is mutated.

Applicant's arguments filed 12/1/05 have been fully considered but they are not persuasive.

Applicant argues that the claims are definite and mutation techniques are taught in the specification. There is no legal requirement to specify how the enzyme is mutated. Modifying an existing protein is one method to make a mutant enzyme. The function of the enzyme is described.

It is the examiner's position that one would not know if some enzyme has been mutated or not in some fashion, therefore one would not know if the enzyme is encompassed by the claims. One could say all naturally occurring enzymes are to some degree the result of some sort of mutation and certainly all non-naturally occurring enzymes would be mutated. More standard terminology may be naturally occurring or wild type enzyme. It is not clear how an existing enzyme distinguishes any enzyme where a mutated enzyme may be further mutated for example. The above rejection does not relate to the function of the enzyme.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1655

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